REMARKS

This is responsive to the Office Action mailed on December 30, 2005.

In that Office Action, claims 1-12, 18-29 and 36-42 were rejected. With this Amendment, claims 1, 2, 4, 6-8, 11, 12, 18, 19, 22, 24, 25, 28, 29, 36, 27, 39, 40 and 42 are hereby amended.

The Office Action continued the objection to claims 2, 4, 19 and 37 as encompassing non-elected embodiments. Applicant believes that in view of the amendments to the linking claims (claims 1, 18 and 36), that the linking claims are now in allowable form, and that the objection to claims 2, 4, 19 and 37 should be removed.

The Office Action next objected to the disclosure because the unit for "250μ" was missing. The Office Action stated that it was not clear if it was meant to be 250μl or 250μg. This typographical error in the disclosure has been corrected to 250μl. In view of this, it is respectfully requested that the objection to the disclosure based on this missing unit be withdrawn.

Next, the Office Action objected based on the Abstract's length. A substitute abstract is enclosed herewith.

Next, the Office Action rejected claims 1, 3, 5-7, 18, 36 and 40-42 under 35 U.S.C. § 112, first paragraph, alleging that the specification as being enabling only for one method of producing a microbial adherence inhibitor does not reasonably provide enablement of a method of producing any microbial adherence inhibitor of any "colony-forming lactic acid producing immunogen". The Office Action has taken the position that the specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. The Office Action does recognize that not all "lactic acid producing immunogen" colonize the intestinal tracts of all food animals and are responsible for the incident of acidosis.

In response, independent claims 1, 18, 36 and 40 have been amended to state that the female birds are inoculated with a lactic acid producing bacteria that colonize in the intestinal tract of the food animal to be treated whose colonization results in acidosis. It is believed that

the specification is enabling for the invention as defined in the amended claims since there are only two known lactic acid producing bacteria that colonize in the intestinal tract of food animals whose colonization results in acidosis. In an article entitled *Acidosis in Cattle: A Review*, Owens et al. discuss on page 279 the *Streptococcus bovis* and *Lactobacilli* are the two bacteria that cause acidosis in cattle. (Exhibit A). This also holds true for horses (Exhibit B), sheep (Exhibits C and D) and camels (Exhibit E).

In view of the amendments, and in view of the fact that there are only two known bacteria that cause acidosis it is respectfully requested that the rejection of claims 1, 3, 5-7, 18, 36 and 40-42 under 35 U.S.C. § 112, first paragraph, be withdrawn.

The Office Action also rejected claims 1, 3, 5-7, 18, 36 and 40-42 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action stated "The specification does not reasonably provide a written description of *any* "lactic acid produced immunogen" for the claimed methods.

As discussed above, independent claims 1, 18, 36 and 40 have been amended to state that the immunogen is a bacteria and that the bacteria is a lactic acid producing bacteria that colonize in the intestinal tract of the food animal to be treated whose colonization results in acidosis. Consequently, the claims no longer include "any" lactic acid producing immunogen". Furthermore, as discussed above with regard to the non-enablement rejection, the number of known lactic acid producing bacteria that colonize in the intestinal tract of food animals whose colonization results in acidosis are all discussed in the application.

The Office Action also stated that "The specification does not disclose the structure of the "SB antigen" from *Streptococcus bovis* without the amino acid sequence. The "SB antigen" from *Streptococcus bovis* as disclosed on page 17 is whole cell bacteria grown in the Brain Heart Infusion (BHI) medium." The Office Action further goes on to state "Given the indefinite number of undisclosed "colony-forming lactic acid producing immunogens", the claimed methods of using the undisclosed immunogens are not adequately described."

In summary, the Office Action states that since the specification only discloses inoculation with *Streptococcus bovis*, *Lactobacillus* or *Fusobacterium necrophorum*, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Based on this the Office Action concludes that applicant was not in possession of the claimed genus.

However, as the literature references discussed previously show, and as previously discussed above with respect to the non-enablement rejection, applicant in fact has provided to the Patent Office a representative sample of the number of species of bacteria that are colony-forming lactic acid producing bacterium that colonize in the intestinal tract of the food animal to be treated. Of course, there are many lactic acid producing bacteria, but only two known bacteria that colonize in the intestinal tract and whose colonization results in acidosis. In view of this, the rejection under 35 U.S.C. § 112, first paragraph, of the claims mentioned above is respectfully requested to be withdrawn.

Next, the Office Action rejected claims 7, 12, and 29 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action states that the phrase "liquid extender" in claims 7, 12 and 29 is ambiguous and indefinite because the specification does not define the term "liquid extender". Therefore, one of ordinary skill in the art cannot appraise the metes and bounds of the claimed invention. Claims 7, 12 and 29 have been amended to state that the liquid extender is palatable to the food animal. Support for this amendment is found in Example 13 which states that the specific whole egg material is collected and mixed with food grade molasses or pure food grade soy bean oil. Example 14 also describes mixing the specific whole egg material mixed with food grade molasses or pure food grade soy bean oil. The term "liquid extender" is simply just that, as disclosed in Examples 13 and 14. It is used to "extend" the antibodies so that they may be spread over a feed product which in turn is then eaten by the food animal to be treated and is palatable to the animal. Such liquid extenders are used to extend many types of nutrients to agricultural animals to minimize cost by using the nutrient (and in this situation, the antibody) efficiently. Such procedures are well known in the

art of feeding high cost nutrients and supplements, for example to cattle. In view of this, and in view of the amendment to these claims, it is believed that the claims comply with 35 U.S.C. § 112, second paragraph, and it is requested that the rejection of claims 7, 12 and 29 be reconsidered, and the rejection removed.

The Office Action also rejected claim 8 due to a typographical error. Claim 8 has been amended in subparagraph b changing the designation "SN" to "SB". Withdrawal of this rejection is respectfully requested.

Claims 2, 4, 6, 11, 19, 22, 24, 28, 37, 39 and 42 are amended to eliminate the Markush claim language and the claims have been changed to claim in the alternative. Alternative claiming is permissible.

Next, the Office Action rejected claims 1-4 and 18-19 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,419,926. Specifically, the Office Action states that the "'926 patent teaches an egg antibody microbial adherence inhibitor to control the incidence of acidosis such as an ulcer caused by lactic acid producing immunogen or bacteria such as *Lactobacillus salivaious, Enterrococcuses, yeasts,* and *Bacillus*" referring to column 6, lines 46-54, in particular. The Office Action states that the microbial inhibitor is provided as a food additive. The Office Action further states that "the reference egg antibody microbial adherence inhibitor is produced by inoculating female birds such as hens with bacteria such as *Lactobacillus salivious, Enterrococcuses, yeasts,* and *Bacillus* referring to column 5, 52-67, in particular.

With all due respect, it is believed that the '926 patent has been misread. The '926 patent describes inoculation of hens with *H. pylori* to produce antibodies that prevent the adhesion of Hp to gastric mucosa and inhibit the growth of Hp in the stomach. The mention of lactic acid bacteria in the '926 patent is the use of such bacteria along with the Hp antibodies to prevent the adhesion of Hp to gastric mucosa and to inhibate the growth of Hp in the stomach. There is no disclosure in the '926 patent of inoculating the hens with lactic acid bacteria. For example, in column 6, lines 60-64 it is stated that:

> "These antibodies [referring to Hp antibodies] can be used in combination with at least one organism selected from lactic acid bacteria, and

> *Enterrococcuses, yeasts and Bacillus* in prevention or treatment of these diseases or can be added to a food for prevention of these diseases."

Further, in Experiment 3, describes the oral administration of *Lactobacillus salivious* and its effect of reducing or eliminating Hp from the stomach. It is the bacteria that are delivered orally and not the antibody to the bacteria.

Therefore, it is believed that the rejection under 35 U.S.C. § 102(e) of claims 1-4 and 18-19 should be reconsidered and withdrawn since the reference does not anticipate the claims.

Next, claims 1-4, 8-9, 18-21, 25-26, 36-37 and 40 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,080,895 in view of U.S. Patent No. 6,287,555. The Office Action states that "The '895 patent teaches a method of producing a microbial adherence inhibitor such as egg antibody that binds specifically to colony-forming immunogen such as *E coli* that inhibits the microbacteria from adhering to the intestinal tract of livestock. The Office Action states that the claimed invention in claim 1 differs from the teachings of the '895 patent only in that the colony-forming immunogen is a lactic acid producing immunogen. In addition, the Office Action states that the invention in claims 2 and 4 differ from the teaching of the reference only in that colony-forming immunogen is from the class of *Streptococcus bovis*.

To overcome this deficiency in the '895 patent, the Office Action then states that the '555 patent teaches microorganisms such as *Streptococcus bovis* as an important lactic acid bacterium in the rumen of livestock which contributes to the development of lactic acidosis. The Office Action further states that the '555 patent teaches the risk of lactic acidosis can be reduced by immunization against *S. bovis* to produce antibody that binds specifically to *S. bovis*. Specifically, the '555 further teaches the immunogens as SB antigen from *Streptococcus bovis* by culturing the bacterium in RSY-II medium. The Office Action then states that:

> "From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in producing the claimed invention."

Applicant's attorney respectfully disagrees. In this Office Action, the position was taken that undisclosed lactic acid bacteria were the basis for both a rejection based on non-enablement and insufficient disclosure since the art was unpredictable such that one skilled in the art would go through undue experimentation. The Office Action stated on page 5:

> "Given the unlimited number of undisclosed lactic acid producing immunogen, it is unpredictable which egg antibody microbial adherence inhibitor produced by immunizing a hen with any undisclosed lactic acid immunogen will have the same antibody specificity as the egg antibody that produced by inoculating the bird the *Streptococcus bovis*, in turn, would be useful for any purpose."

Having stated the above, now the Office Action combines the teachings of one reference with regard to *E coli* (which is far from a lactic acid producing bacteria) combines it with another reference that simply teaches the use of an antibody to *S. bovis* and says that the result is obvious and predictable. How can it be unpredictable in one case and predictable in another.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Applicant would like to address the second criteria without acknowledging that the first and third criteria have been met, since applicant believes that only a discussion of the second criteria is necessary to obviate the rejection under 35 U.S.C. § 103(a).

As the Board of Appeals for the Federal Circuit stated in *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 93-94 (Fed. Cir. 1986):

> "Taken as a whole, the court's comments on § 112 . . . are internally inconsistent . . . . . The District Court itself said that the "method for producing monoclonal antibodies in vitro was well known prior to the alleged invention" . . . . The court then about-faced and held that the '110 patent deficient because it fails to teach how to make monoclonal antibodies." *Id.*

In other words, the court held that one cannot conclude that a given embodiment is simultaneously obvious under § 103(a) and then not enabled under § 112, first paragraph.

The Office Action states, on page 10, that "From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. One having ordinary skill in the art would have been motivated to do this because *Streptococcus bovis* is an important lactic acid bacterium in the rumen of livestock which contributes to the development of lactic acidosis and the risk of lactic acidosis can be reduced by antibody that binds specifically to *S. bovis* as taught by the '555 patent . . .

The Office Action states that "the motivation is there because *Streptococcus bovis* is an important lactic acid bacteria in the rumen of livestock". The Office Action does not need to cite the '555 patent for that proposition. The fact that *S. bovis* is an important lactic acid bacteria was well known since the early 1970s, if not earlier. Of course, the making of antibodies to *S. bovis* is old. However, the fact that *S. bovis* is an important lactic acid bacteria in the rumen of livestock does not in and of itself include a motivation to do what applicant has done. There must be a reason or suggestion in the art for selecting the procedure used other than the knowledge learned from applicant's disclosure. *In re Dow Chemical*, 5 U.S.P.Q. 2d 1529, 1532 (CAFC 1988). In essence the standard that the Office Action is using based on the importance of *S. bovis* as a lactic acid producing bacterium in the rumen of livestock is that it would be obvious to try the procedure disclosed in the '895 patent with *S. bovis*. An obvious to try standard is not an acceptable standard as discussed in the MPEP. This is especially true in the present situation, in which the '895 patent describes a procedure using an entirely different species of bacterium of an entirely different genus, while the '555 patent describes making an antibody using another species of bacteria in yet an entirely different genus. The unpredictability in this art is well known. It is believed, that the Office Action has not made a case of *prima facie* obviousness. In view of this, it is respectfully requested that the rejection under 35 U.S.C. § 103(a) be withdrawn for claims 1-4, 8-9, 18-21, 25-26, 36-37 and 40 and the claims allowed.

Lastly, the Office Action then rejected claims 5-7, 10-12, 22-24, 27-29, 38-39 and 41-42 as being unpatentable over the '895 patent in view of the '555 patent as applied to claims 1-4, 8-9, 18-21, 25-26, 36-37 and 40 as mentioned previously, and in further view of U.S. Patent Nos. 4,748,018, 3,878,298 and 4,166,867.

Based on the discussion with regard to the combination of the '895 patent with the '555 patent, it is believed that this rejection under 35 U.S.C. § 103(a) cannot also be maintained, for the reasons previously stated. Therefore, it is respectfully requested that the rejection of claims 5-7, 10-12, 22-24, 27-29, 38-39 and 41-42 be reconsidered and the claims allowed.

In view of the above, it is believed that the claims are now all in allowable form. Reconsideration and allowance of all of the claims are respectfully requested.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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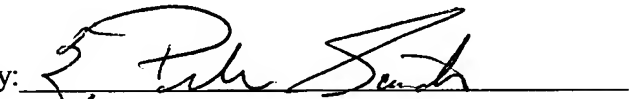
By: 

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